

**REMARKS/ARGUMENTS**

**INTRODUCTORY COMMENTS:**

In a previous Office Action, the Examiner withdrew claims 11-18, 50-53, 55 and 57-80 from consideration as a result of a restriction requirement and an election of species. In addition, the Examiner objected to the drawings. Furthermore, the Examiner rejected the claims under 35 U.S.C. §112, second paragraph, as indefinite. The Examiner also issued a number of art-based rejections over U.S. Patent No. 5,874,214 to Nova et al. (“Nova”), U.S. Patent No. 6,342,349 to Virtanen et al. (“Virtanen”) and U.S. Patent No. 5,922,617 to Wang et al. (“Wang”).

As a result of applicants’ response, the Examiner acknowledged and entered applicants’ amendment, approved of applicants’ proposed drawing correction, and withdrew her rejections under 35 U.S.C. §112, second paragraph. Having inadvertently failed to withdraw claims 50-53 in the previous Office Action, the Examiner also withdrew claims 50-53 from consideration as a result of the restriction requirement in Paper No. 7, noting applicants traverse.

Nevertheless, the following art-based rejections are maintained:

(1) Claims 1, 3-10, 19-33, 38-49, 54 and 56 are rejected under 35 U.S.C. §102(b) as anticipated by Nova;

(2) Claims 1, 43, and 56 stand rejected under 35 U.S.C. §102(e) as anticipated by Virtanen; and

(3) Claims 1 and 34-37 stand rejected under 35 U.S.C. §103(a) as obvious over Nova in view of Wang.

With respect to the corrections to the drawing, applicants submit herewith a replacement sheet that contains the corrections approved by the Examiner.

A telephonic interview was held on July 15, 2003 between the Examiner and the applicants’ representative. Applicants thank the Examiner for clarifying her position in the interview. The claim rejections and related issues raised by the Examiner during the interview are addressed in part by the above amendments and are otherwise traversed for reasons that are discussed in detail below.

**THE ABOVE AMENDMENTS:**

Independent claims 1, 54 and 56 have been amended to clarify the inventive subject matter and to expedite prosecution. Each of these claims have been reworded to set forth a device comprising a substrate having an *integrated indicator having a structure that exhibits a detectable response to a condition, wherein the indicator structure continues to exhibit the detectable response for at least one minute after removing the device from the condition.*

Various indicators having such a structure are described, for example, on page 20, line 27, to page 26, line 7. These sections, particularly the subsection on page 20, line 30, to page 21, line 27, also provide support for new claims 81-84, which are added to set forth exemplary indicator structures encompassed by claim 1. Since claim 3 depends from claim 1, claim 3 has been amended so as to render its terminology consistent with that of claim 1. Accordingly, no new matter has been added by way of these amendments.

These amendments are made for the sole purpose of clarification. Accordingly, the independent claims remain unaltered in scope, and the amendments do not introduce any new issues. In addition, these amendments put the claims in better shape for appeal, should an appeal be necessary. Accordingly, applicants respectfully request entry of the amendments.

**STATUS OF THE CLAIMS**

Upon entry of the above amendment, claims 1, 3-58, and 81-84 are pending, claims 81-84 are added, claims 1, 3, 54, and 56 are amended, and claims 4-53, 55, 57 and 58 are unchanged from the previous Office Action.

**THE 35 U.S.C. §102(B) REJECTION OF CLAIMS 1, 3-10, 19-33, 38-49, 54, AND 56 AS ANTICIPATED BY NOVA:**

Claims 1, 3-10, 19-33, 38-49, 54 and 56 remain rejected as anticipated by Nova. In support of the rejection, the Examiner repeats her reasoning from the previous Office Action. In addition, the Examiner states that the prolonged detectability of the indicator response “does not bear any patentable weight.” In support, the Examiner cites cases from the years of 1935 to 1969, which predate the establishment of the Federal Circuit. Instead of addressing the differences between the claimed subject matter and the teachings of the cited art as pointed out

by applicants, the Examiner's apparent position is that, as a matter of law, all nonstructural elements of device claims may be ignored as bearing no patentable weight, and that the prolonged detectability of the indicator response is a functional element rather than a structural element.

As an initial matter, applicants disagree with the Examiner's legal rationale because it is well settled under Federal Circuit law that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed Cir. 1987). Since proper anticipation analysis requires careful consideration of *all* claim elements, no element in a claim may be summarily ignored simply by classifying the element as "functional" rather than "structural." See, e.g., *In re Gulack* 217 USPQ 401 (Fed Cir. 1983), *In re Lowry*, 32 USPQ2d 1031 (Fed. Cir. 1994), *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997). In particular, the Federal Circuit has specifically stated: "A patent applicant is free to recite features of an apparatus either structurally or functionally." *Schreiber*, 44 USPQ2d at 1432. Thus, applicants submit that whether an element is structural or functional is at best tangential to whether the element carries "patentable weight." Instead, the "patentable weight" carried by an element corresponds to whether the element is disclosed or suggested in the prior art. See *Id.* at 1431. That is, ***a claim element carries no patentable weight only if the element is disclosed or suggested in the prior art.***

Thus, assuming *arguendo* that the cases cited by the Examiner represented good law before the establishment of the Federal Circuit, they are no longer relevant. In addition, regardless whether the prolonged indicator response element is structural or functional, applicants respectfully submit that the Examiner has erred by ignoring the element completely and failing to recognize the difference between the claimed subject matter and the teachings of the cited art. That is, in order for the Examiner to issue a valid anticipation rejection based on *Nova*, the Examiner must state why she thinks *Nova* teaches all elements of the pending claims, ***including the prolonged detectable response element.*** So far, the Examiner has failed to do so.

As discussed in applicants' previous response, all pending independent claims are directed to devices each having at least one integrated indicator that exhibits ***a prolonged detectable response*** when exposed to a condition. That is, ***the indicator continues to exhibit the***

*response for at least one minute after the device is removed from the condition.* This feature is clearly absent from Nova. That is, this feature is neither expressly nor inherently disclosed in Nova. Although Nova describes the use of a temperature sensor, there is no disclosure relating to whether the response of the temperature sensor to a particular temperature is detectable after the temperature sensor is removed from the particular temperature environment. Instead, one of ordinary skill in the art would read Nova as describing a temperature sensor for “real-time” temperature monitoring. Such “real-time” temperature monitoring does not involve an indicator response to a condition that is detectable after the indicator is removed from the condition.

In addition, this feature renders all claims nonobvious over Nova. As pointed out by the Examiner, Nova describes a combination of a matrix with a memory in which a temperature-sensing device may be provide that is electrically connected to the recording device for recording the temperature detected by the sensing device. As further discussed in Nova in column 8, lines 48-52, an electrical signal may be generated as a result which allows the recording device to be written to in less than five seconds, most preferably in about 1 millisecond or less. Thus, Nova merely describes a combination of a matrix with a recording device in which the temperature-sensing device, upon exposure to a particular temperature, responds by instantaneously generating a *transient* electrical signal. The transient electrical signal, in turn, may be written to the recording device. While the recording device may serve to provide a record of the particular temperature experience by the temperature-sensing device, *the response of the temperature of the temperature-sensing device, i.e., transient electrical signal itself, would not be detectable for at least one minute after the temperature-sensing device is removed from the particular temperature.* Thus, Nova does not suggest a device comprised of a substrate having an integrated indicator that exhibits a prolonged and detectable response.

Notably, it is disclosed in applicant’s specification in the paragraph bridging pages 25 and 26 that structures having a prolonged or permanent response are preferred over a transient or quickly reversible response. In contrast, Nova describes a combination of a matrix with a recording device, wherein the recording device may record the particular temperature to which the temperature-sensing device has been exposed. With such a record, one skilled in the art would not think that there would be any need for the response of the temperature-sensing device itself to remain detectable. In particular, one skilled in the art, upon reading Nova, would not

recognize a need for the electrical signal to be generated and detectable for over one minute. Given that Nova teaches a programmable recording device that appears to be a critical element of the described combination and that a shorter programming time is preferred over a longer programming time, Nova effectively teaches away from an indicator that exhibits a prolonged detectable response. One of ordinary skill in the art would recognize that the prolonged detectable response element does not represent a routine modification of a known device, because Nova teaches away from an indicator that exhibits a prolonged detectable response.

By characterizing the prolonged detectable response claim element as a structural rather than a functional limitation, the Examiner appears to have issued a rejection that is based on *semantic* concerns and the misclassification of the prolonged detectable response element as a nonstructural limitation. In response, applicants initially note that they are unaware of any indicator that does not have a structure. In addition, it is also well established Federal Circuit law that claims are to be interpreted in light of the specification, and the specification is replete with disclosure that sets forth indicator structures which exhibit prolonged rather than transient responses. Accordingly, one of ordinary skill in the art would recognize that the prolonged detectable response element recited in the claims qualifies as a structural element when viewed in proper context rather than summarily ignored.

Furthermore, the ordinary artisan would recognize that indicators which exhibit a transient response must differ in structure from indicators which exhibit a prolonged or permanent response. That is, indicators having the same structure must behave in the same manner under the same condition, and indicators that exhibit differing response behavior under the same condition must be structurally different. Since the indicators of Nova exhibit a transient response while the indicators of the pending claims exhibit a prolonged response or permanent response, the indicators of Nova must differ in structure from the indicators recited in the claims.

Nevertheless, to expedite prosecution and to clarify the inventive subject matter, applicants have reworded the independent claims to recite that the integrated indicator has a *structure* that exhibits a detectable response when exposed to a condition, wherein *the indicator structure continues to exhibit the detectable response for at least one minute after removing the device from the condition*. While this rewording does not alter the scope of the claims, it should address the Examiner's concerns regarding claim semantics.

To further emphasize the structural nature of the prolonged indicator response, applicants have added new claims 81-84. These claims set forth exemplary temperature-sensitive indicator structures that may exhibit a prolonged indicator response. As claims 81-84 incorporate all elements of the claim 1 from which they ultimately depend, they do not encompass subject matter that lies outside the scope of claim 1 and therefore raise no new issues.

Thus, applicants respectfully request reconsideration and withdrawal of this rejection.

**THE 35 U.S.C. §102(E) REJECTION OF CLAIMS 1, 43, AND 56 AS ANTICIPATED BY VIRTANEN:**

Claims 1, 43, and 56 remain rejected as anticipated by Virtanen. In maintaining this rejection, the Examiner repeats her reasoning from the previous Office Action and again asserts that the prolonged detectable response element is a functional element that carries no patentable weight.

Applicants traverse this rejection because, as discussed in the previous response, Virtanen simply does not contain any disclosure relating to an integrated indicator. In addition, this semantic rejection suffers from the same flaws as the rejection over Nova. Thus, for the same reasons as discussed above, applicants respectfully request reconsideration and withdrawal of this rejection as well.

**THE 35 U.S.C. §103(A) REJECTION OF CLAIMS 1 AND 34-37 AS OBVIOUS OVER NOVA IN VIEW OF WANG:**

Claims 1 and 34-37 also remain rejected as obvious over Nova in view of Wang. In maintaining this rejection, the Examiner repeats her reasoning from the previous Office Action. In addition, the Examiner mischaracterizes applicants remarks by stating on page 8 of the Office Action that applicants argued that Nova in view of Wang “do not anticipate the presently claimed device.”

As an initial matter and with all due respect, applicants have made no argument that would suggest that an anticipation rejection may be properly issued over a combination of references. Applicants are fully aware that an anticipation rejection should be supported by no more than a single reference. The rare exceptions to the single-reference requirement as set forth in MPEP §2131.01 are inapplicable in this instance.

In addition, applicants again traverse this rejection because Nova, the primary reference relied upon by the Examiner, neither anticipates nor suggests the invention as claimed, regardless whether the prolonged detectable response element is functional or structural. Furthermore, Wang does not cure the deficiencies of Nova. Thus, Nova in view of Wang does not render any pending claims obvious and withdrawal of this rejection is warranted.

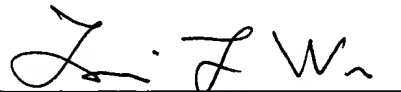
CONCLUSION

For all of the above reasons, it is submitted that the pending claims define an invention that is patentable over the art. As the application should now be in condition for allowance, a prompt indication to that effect would be appreciated.

If the Examiner has any questions concerning this communication, she is welcome to contact the undersigned attorney at (650) 330-0900.

Respectfully submitted,

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